

CLAIMS:

1. A method for monitoring 85P1B3 gene products in a biological sample from a patient who has or who is suspected of having cancer, the method comprising:

5 determining the status of 85P1B3 gene products expressed by cells in a tissue sample from an individual;

comparing the status so determined to the status of 85P1B3 gene products in a corresponding normal sample; and,

10 identifying the presence of aberrant 85P1B3 gene products in the sample relative to the normal sample.

2. A method of monitoring the presence of cancer in an individual comprising: performing the method of claim 1 whereby the presence of elevated 85P1B3 mRNA or protein expression in the test sample relative to the normal tissue sample indicates the presence or status of a cancer.

15 3. The method of claim 2, wherein the cancer occurs in a tissue set forth in Table I.

4. A composition comprising:  
a substance that modulates the status of 85P1B3, or a molecule that is modulated by 85P1B3 whereby the status of a cell that expresses 85P1B3 is modulated.

20 5. The composition of claim 4, further comprising a pharmaceutically acceptable carrier.

6. A pharmaceutical composition that comprises the composition of claim 4 in a human unit dose form.

25 7. A composition of claim 4 wherein the substance comprises a 85P1B3-related protein.

8. The composition of claim 7, further comprising antigen presenting cells.

30 9. The composition of claim 7 comprising an analog peptide of eight, nine ten or eleven contiguous amino acids of Figure 2 (SEQ ID NO.: \_\_\_\_).

10. A composition of claim 7 comprising a CTL polypeptide epitope from Figure 2 (SEQ ID NO.: \_\_\_\_).

35 11. The composition of claim 10, wherein the CTL epitope comprises a polypeptide selected from Tables V-XVIII.

12. A composition comprising a peptide region of at least 5 amino acids of Figure 2 (SEQ ID NO.: \_\_\_\_ ) in any whole number increment up to 229 that includes an amino acid position selected from: an amino acid position having a value greater than 0.5 in the Hydrophilicity profile of Figure 5, an amino acid position having a value less than 0.5 in the Hydrophaticity profile of Figure 6; an amino acid position having a value greater than 0.5 in the Percent Accessible Residues profile of Figure 7; an amino acid position having a value greater than 0.5 in the Average Flexibility profile on Figure 8; or an amino acid position having a value greater than 0.5 in the Beta-turn profile of Figure 9.

10 13. A polynucleotide that encodes an analog peptide of claim 9.

14. A composition of claim 4 wherein the substance comprises an antibody or fragment thereof that specifically binds to a 85P1B3-related protein.

15 15. The antibody or fragment thereof of claim 14, which is monoclonal.

16. A recombinant protein comprising the antigen-binding region of a monoclonal antibody of claim 15.

20 17. The antibody or fragment thereof of claim 14, which is labeled with a detectable marker.

18. The recombinant protein of claim 16, which is labeled with a detectable marker.

25 19. The antibody fragment of an antibody of claim 14, which is an Fab, F(ab')<sub>2</sub>, Fv or sFv fragment.

20. The antibody of claim 14, which is a human antibody.

30 21. The recombinant protein of claim 16, which comprises murine antigen binding region residues and human constant region residues.

22. A non-human transgenic animal that produces an antibody of claim 14.

23. A hybridoma that produces an antibody of claim 15.

35 24. A single chain monoclonal antibody that comprises the variable domains of the heavy and light chains of a monoclonal antibody of claim 15.

25. A vector comprising a polynucleotide that encodes a single chain monoclonal antibody of claim 24 that immunospecifically binds to a 85P1B3-related protein.

26. A method of delivering a cytotoxic agent to a cell that expresses 85P1B3, said method comprising:

providing a cytotoxic agent conjugated to an antibody or fragment thereof of claim 14; and, exposing the cell to the antibody-agent conjugate.

27. A composition of claim 4 wherein the substance comprises a polynucleotide that encodes a single chain monoclonal antibody that immunospecifically binds to an 85P1B3-related protein.

28. A composition of claim 4 wherein the substance comprises a polynucleotide that comprises an 85P1B3-related protein coding sequence.

29. A composition of claim 28 comprising a polynucleotide from position number 13 through number 702 of Figure 2 (SEQ ID NO.: \_\_\_\_).

30. The composition of claim 29, wherein T is substituted with U.

31. A composition of claim 28 comprising the polynucleotide of Figure 2 (SEQ ID NO.: \_\_\_\_ ) in a human unit dose form.

32. The composition of claim 31, wherein T is substituted with U.

33. A composition of claim 28 comprising a polynucleotide that encodes an 85P1B3-related protein that is at least 90% homologous to the entire amino acid sequence shown in Figure 2 (SEQ ID NO.: \_\_\_\_).

34. The composition of claim 33, wherein the polynucleotide encodes an 85P1B3-related protein that is at least 90% identical to the entire amino acid sequence shown in Figure 2 (SEQ ID NO: \_\_\_\_).

35. A composition of claim 28 comprising a polynucleotide that encodes at least one peptide set forth in Tables V-XVIII.

36. A composition of claim 28 comprising a polynucleotide that encodes a peptide region of at least 5 amino acids of Figure 2 (SEQ ID NO.: \_\_\_\_ ) in any whole number increment up to 299 that includes an

amino acid position selected from: an amino acid position having a value greater than 0.5 in the Hydrophilicity profile of Figure 5, an amino acid position having a value less than 0.5 in the Hydropathicity profile of Figure 6; an amino acid position having a value greater than 0.5 in the Percent Accessible Residues profile of Figure 7; an amino acid position having a value greater than 0.5 in the Average Flexibility profile on Figure 8; or an amino acid position having a value greater than 0.5 in the Beta-turn profile of Figure 9.

37. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 29.

38. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 30.

39. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 31, in human unit dose form.

40. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 32.

41. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 33.

42. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 34.

43. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 35.

44. A pharmaceutical composition of claim 4 wherein the substance comprises a ribozyme that cleaves a polynucleotide having 85P1B3 coding sequence and a physiologically acceptable carrier.

45. A pharmaceutical composition of claim 4 wherein the substance comprises human T cells, wherein said T cells specifically recognize an 85P1B3 peptide sequence in the context of a particular HLA molecule.

46. A method of inhibiting growth of cancer cells that expresses 85P1B3, the method comprising: administering to the cells the composition of claim 4.

47. A method of claim 46 of inhibiting growth of cancer cells that express 85P1B3, the method comprising steps of:

administering to said cells an 85P1B3-related protein.

5 48. A method of claim 46 of inhibiting growth of cancer cells that express 85P1B3, the method comprising steps of:

administering to said cells an antibody or fragment thereof that specifically binds to a 85P1B3-related protein.

10 49. A method of claim 46 of inhibiting growth of cancer cells that express 85P1B3, the method comprising steps of:

administering to said cells a vector that encodes a single chain monoclonal antibody that immunospecifically binds to an 85P1B3-related protein.

15 50. A method of claim 46 of inhibiting growth of cancer cells that express 85P1B3, the method comprising steps of:

administering to said cells a vector that comprises a polynucleotide comprising a 85P1B3-related protein coding sequence.

20 51. A method of claim 46 of inhibiting growth of cancer cells that express 85P1B3, the method comprising steps of:

administering to said cells an antisense polynucleotide complementary to a polynucleotide having a 85P1B3 coding sequence.

25 52. A method of claim 46 of inhibiting growth of cancer cells that express 85P1B3, the method comprising steps of:

administering to said cells a ribozyme that cleaves a polynucleotide having 85P1B3 coding sequence.

30 53. A method of claim 46 of inhibiting growth of cancer cells that express 85P1B3 and a particular HLA molecule, the method comprising steps of:

administering to said cells human T cells, wherein said T cells specifically recognize an 85P1B3 peptide sequence in the context of the particular HLA molecule.

35 54. A method of treating a patient who bears cancer cells that expresses 85P1B3, the method comprising:

administering to the patient the composition of claim 4.



administering to said patient human T cells, wherein said T cells specifically recognize an 85P1B3 peptide sequence in the context of the particular HLA molecule.

5 63. A method of generating a mammalian immune response directed to 85P1B3, the method comprising:

exposing cells of the mammal's immune system to an immunogenic portion of an 85P1B3-related protein or a nucleotide sequence that encodes said protein, whereby an immune response is generated to 85P1B3.

10 64. A method of inducing an immune response of claim 63, said method comprising:  
providing a 85P1B3-related protein that comprises at least one T cell or at least one B cell epitope;  
contacting the epitope with a mammalian immune system T cell or B cell respectively, whereby the T cell or B cell is induced.

15 65. The method of claim 64, wherein the immune system cell is a B cell, whereby the induced B cell generates antibodies that specifically bind to the 85P1B3-related protein.

20 66. The method of claim 64, wherein the immune system cell is a T cell that is a cytotoxic T cell (CTL), whereby the activated CTL kills an autologous cell that expresses the 85P1B3 protein.

25 67. The method of claim 64, wherein the immune system cell is a T cell that is a helper T cell (HTL), whereby the activated HTL secretes cytokines that facilitate the cytotoxic activity of a CTL or the antibody producing activity of a B cell.

30 68. An assay for detecting the presence of a 85P1B3-related protein or polynucleotide in a biological sample from a patient who has or who is suspected of having cancer, comprising steps of:  
contacting the sample a substance of claim 4 that specifically binds to the 85P1B3-related protein or polynucleotide, respectively; and,  
determining that there is a complex of the substance and 85P1B3-related protein or the substance and 85P1B3-related polynucleotide, respectively.

35 69. An assay of claim 68 for detecting the presence of a 85P1B3-related protein in a biological sample from a patient who has or who is suspected of having cancer, comprising steps of:  
contacting the sample with an antibody that specifically binds to the 85P1B3-related protein; and,  
determining that there is a complex of the antibody and 85P1B3-related protein.

70. The assay in accordance with claim 68 further comprising the step of:

obtaining a sample from a patient who has or who is suspected of having cancer.

71. The assay of claim 68 for detecting the presence of an 85P1B3 polynucleotide in a biological sample, comprising:

- 5       contacting the sample with a polynucleotide probe that specifically hybridizes to a polynucleotide encoding an 85P1B3-related protein having the amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_); and,  
      detecting the presence of a hybridization complex formed by the hybridization of the probe with 85P1B3 polynucleotide in the sample, wherein the presence of the hybridization complex indicates the presence of 85P1B3 polynucleotide within the sample.

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72. An assay in accordance with claim 68 for detecting the presence of 85P1B3 mRNA in a biological sample from a patient who has or who is suspected of having cancer, said method comprising:

- (a) producing cDNA from the sample by reverse transcription using at least one primer;  
      (b) amplifying the cDNA so produced using 85P1B3 polynucleotides as sense and antisense primers,  
15    wherein the 85P1B3 polynucleotides used as the sense and antisense primers are capable of amplifying 85P1B3 cDNA; and  
      (c) detecting the presence of the amplified 85P1B3 cDNA.

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